

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE PATENT OPERATION

In re Application of:

Xie et al.

Serial No.: 10/822,627

Group Art Unit: --

Filed: April 12, 2004

Examiner: --

For: CONTROLLED RELEASE OPIOD ANALGESIC FORMULATION

New York, NY 10036 June 21, 2004

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT

Sir:

The following statement of relevance is submitted with the accompanying Form PTO/SB/08A.

Document

Designation

Relevance

AA

Relates to a slow release pharmaceutical composition.

U.S.P. 4,235,870

AB

Relates to an osmotic device with hydrogel driving member.

U.S.P. 4,327,725

AC

Relates to an extended action controlled release composition.

U.S.P. 4,443,428

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope

addressed to:

Commissioner for Patents

P.O. Box 1450

Alexamdria, VA 22313-1450

on June 21, 2004

Martin P. Endres, Reg. No. 35,498

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Document Designation AD U.S.P. 4,569,937	Relevance Relates to an analgesic mixture of oxycodone and ibuprofen.
AE U.S.P. 4,581,225	Relates to a sustained release intranasal formulation and method of use thereof.
AF U.S.P. 4,612,008	Relates to an osmotic device with dual thermodynamic activity.
AG U.S.P. 4,626,539	Relates to a transdermal delivery of opioids.
AH U.S.P. 4,783,337	Relates to an osmotic system comprising plurality of members for dispensing drug.
AI U.S.P. 4,861,598	Relates to a controlled release base for pharmaceuticals.
AJ U.S.P. 4,879,297	Relates to fatty acids and their small chain esters as penetration enhancers in aqueous systems.
AK U.S.P. 4,970,075	Relates to a controlled release base for pharmaceuticals.
AL U.S.P. 5,082,668	Relates to a controlled-release system for pharmaceuticals with a constant pushing source.
AM U.S.P. 5,266,331	Relates to a controlled release oxycodone composition.
AN U.S.P. 5,478,577	Relates to a method of treating pain by administering a 24 hour oral opioid formulation that exhibits a rapid rate of initial rise of plasma drug level.
AO U.S.P. 5,508,042	Relates to a controlled release oxycodone composition.
AP U.S.P. 5,549,912	Relates to a controlled release oxycodone composition.
AQ U.S.P. 5,656,295	Relates to a controlled release oxycodone composition.
AR U.S.P. 5,672,360	Relates to a method of treating pain by administering a 24 hour oral opioid formulation.

BA

21: 2

Relates to a controlled release matrix for pharmaceuticals.

EP 0 698 389

CA

Relates to oxycodone formulation.

55<sup>th</sup> Edition 2001 Physicians' Desk Reference pgs. 2697-2701

In accordance with current Patent and Trademark Office practice no copy of the above listed United States Patents are filed herewith as well as copies of abstracts in English. Full text copies of all non-United States Patent prior art are enclosed herewith. It is respectfully requested that this art be considered by the Examiner in the above-entitled application and made of record therein.

It is respectfully requested that this art be considered by the Examiner in the above-entitled application and made or record therein. It is believed that no fee is required for submission of this Information Disclosure Statement under 37 C.F.R. §1.97(b). However, if a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 08-1540.

Respectfully submitted,

Martin P. Endres

Reg. No. 35,498

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PTO/SB/08A (08-03)
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INFORMATION DISCLOSURE

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JUN 23 2004

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STATEMENT BY APPLICANT (Use as many sheets as necessary)

Complete if Known				
Application Number	10/822,627			
Filing Date	April 12, 2004			
First Named Inventor	Jianbo Xie			
Art Unit				
Examiner Name				
Attorney Docket Number	141-400			

U. S. PATENT DOCUMENTS Pages, Columns, Lines, Where Name of Patentee or Cite Document Number Examiner Relevant Passages or Relevant Initials\* MM-DD-YYYY Applicant of Cited Document Figures Appear Number-Kind Code<sup>2 (# known)</sup> US- 4,235,870 11-25-1980 Leslie AA US- 4,327,725 Cortese et al. 05-04-1982 AB AC US- 4.443.428 04-17-1984 Oshlack et al. <sup>US-</sup> 4,569,937 02-11-1986 Baker et al. AD US- 4,581,225 04-08-1986 Su et al. AΕ AF US- 4,612,008 09-16-1986 Wong et al. <sup>US-</sup> 4,626,539 12-02-1986 Aungst et al. AG US- 4,783,337 11-08-1988 Wong et al. AH US- 4,861,598 08-29-1989 Oshlack ΑI US- 4,879,297 11-07-1989 Mahjour et al. AJ <sup>US-</sup> 4.970,075 Oshlack 11-13-1990 ΑK Wong et al. <sup>US-</sup> 5,082,668 01-21-1992 ΑL <sup>US-</sup> 5,266,331 Oshlack et al. 11-30-1993 AM US- 5,478,577 12-26-1995 Sackler et al. AN US- 5,508,042 04-16-1996 Oshlack et al. AO US- 5.549.912 08-27-1996 Oshlack et al. AP Oshlack et al. <sup>US-</sup> 5,656,295 08-12-1997 AQ US-5,672,360 09-30-1997 Sackler et al. AR

Examiner	Cite	Foreign Patent Document	IGN PATENT DOCU	Name of Patentee or	Pages, Columns, Lines,	Π
Initials*	No.1	Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages Or Relevant Figures Appear	T
_	ВА	EP 0 698 389 A1	02-28-1996	Krishnamurthy		
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Examiner	Date Considered	
Signature	Considered	

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Substitute for form 1449/PTO				e required to respond to a collection of information unless it contains a valid OMB control number.  Complete if Known		
Cassilate for form 1443/170				Application Number	10/822,627	
INF	ORMATION	DIS	CLOSURE	Filing Date	April 12, 2004	
(Use as many sheets as necessary)			PPLICANT	First Named Inventor	Jianbo Xie	
				Art Unit		
			iecessary)	Examiner Name		
Sheet	2	of	2	Attorney Docket Number	141-400	

	NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*							
	CA	55th Edition 2001, Physician's Desk Reference pgs. 2697-2701.					

Examiner	Date	
Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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